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Linda S. Jernigan  
Name  
Linda S. Jernigan  
Signature

P&G Case 9129L

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :  
Jandacek et al. : Confirmation No.  
Serial No. 10/699,351 : Group Art Unit  
Filed October 31, 2003 : Examiner

For Compositions, Methods And Kits Useful For the Alleviation Of Gastrointestinal Effects

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1.  **37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)**

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2.  37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3.  37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). Applicants have not received a first Office Action after filing a Request For Continued Examination (RCE). Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4.  37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5.  Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case). This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

(1) **(For use with applications filed prior to or on June 30, 2003.)** Copies of the cited documents are enclosed.

OR

(2) **(For use with applications filed after June 30, 2003.)** In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

OR

(3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. \_\_\_\_, U.S. Patent Application Serial No. \_\_\_, filed \_\_\_. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR

(4) Copies of all said documents, except Cite Numbers \_\_\_\_\_, were submitted and considered in parent application U.S. Patent Application Serial No. \_\_\_\_\_, filed \_\_\_\_\_. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

(5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

(6) Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

Additional information is attached.

Respectfully submitted,

By Kelly L. McDow-Dunham

Kelly L. McDow-Dunham  
Attorney or Agent for Applicant(s)  
Registration No. 43,787  
(513) 622-3236

Date: February 6, 2004  
Customer No. 27752  
(9129L IDS.doc) (Last Revised 10/10/03)

**CO-PENDING U.S. APPLICATIONS**

Entire copies of all co-pending applications (or the portion of the application and claims that caused it to be cited) must be sent with the IDS (see 37 CFR 1.98(a)(2)(iii))

Atty. Docket No.    Serial Number    Inventor(s)    Filing Date

[Only applications that remain pending at the time of submitting this IDS should be listed here. For applications in which patents have issued, the granted patents should be listed on Form PTO/SB08.]

Please type a plus sign (+) inside this box → [+]

PTO/SB08A (08-03)

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FEB 06 2004

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

SHEET 1 of 2

### COMPLETE IF KNOWN

Application Number	9129L
Confirmation Number	
Filing Date	October 31, 2003
First Named Inventor	Jandacek et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	9129L

### U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	CITE NO. <sup>1</sup>	DOCUMENT NUMBER Number - Kind Code <sup>2</sup> (If known)	PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	PAGES, COLUMNS, LINES WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
	1	US-3,923,976	12-02-1975	Regife Vega et al.	
	2	US-3,980,968	09-14-1976	Ma	
	3	US-4,211,765	07-08-1980	Johnson et al.	
	4	US-4,223,023	09-16-1980	Furda	
	5	US-4,340,699	07-20-1982	Grouiller	
	6	US-4,432,968	02-21-1984	Page et al.	
	7	US-4,598,089	07-01-1986	Hadvary et al.	
	8	US-5,149,720	09-22-1992	DesMarais et al.	
	9	US-5,189,070	02-22-1993	Brownscombe et al.	
	10	US-5,260,345	11/09/1993	DesMarais et al.	
	11	US-5,268,224	12-07-1993	DesMarais et al.	
	12	US-5,290,820	03-01-1994	Brownscombe et al.	
	13	US-5,387,207	02-07-1995	Dyer et al.	
	14	US-5,447,953	09-05-1995	Isler et al.	
	15	US-5,453,282	09-26-1995	Kanauchi et al.	
	16	US-5,563,179	10-08-1996	Stone et al.	
	17	US-5,650,222	07-22-1997	DesMarais et al.	
	18	US-5,741,518	04-21-1998	Ribier et al.	
	19	US-5,817,704	10-06-1998	Shiveley et al.	
	20	US-5,827,909	10-27-1998	DesMarais	
	21	US-6,030,953	02-29-2000	Bailly et al.	
	22	US-6,207,724 B1	03-27-2001	Hird et al.	
	23	US-6,624,161 B2	09-23-2003	Hodson et al.	

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 37 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE  
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FEB 06 2004

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

SHEET 2 of 2

COMPLETE IF KNOWN	
Application Number	10/699351
Confirmation Number	
Filing Date	October 31, 2003
First Named Inventor	Jandacek et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	9129L

## FOREIGN PATENT DOCUMENTS

		<u>FOREIGN PATENT DOCUMENT</u>			Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
EXAMINER INITIALS*	Cite No. <sup>1</sup>	Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	24	W0 00/40569	A1		07-13-2000	Alizyme Therapeutics Ltd.	
	25	W0 99/34787	A2		07-15-1999	Geltex Pharmaceuticals, Inc.	
	26	W0 00/40247	A1		07-13-2000	Alizyme Therapeutics Ltd.	
	27	W0 00/40569	A1		07-13-2000	Alizyme Therapeutics Ltd.	
	28	W0 01/53278	A1		07-26-2001	Alizyme Therapeutics Ltd.	
	29	W0 00/09122	A1		02-24-2000	F. Hoffmann-LaRoche AG	
	30	W0 98/22072	A1		05-28-1998	The Procter & Gamble Co.	
	31	W0 02/074343	A2		09-26-2002	The Procter & Gamble Co.	

## NON PATENT LITERATURE DOCUMENTS

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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